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| APPLICATION NO.       | FILING DATE                   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/587,099            | 12/04/2008                    | Janel A. Birk        | 17951US PCT (HEA)   | 9529             |
| 51957<br>ALLERGAN, I  | 7590 09/16/201<br><b>NC</b> . |                      | EXAMINER            |                  |
| 2525 DUPONT           | DRIVE, T2-7H                  |                      | RYCKMAN, MELISSA K  |                  |
| IRVINE, CA 92612-1599 |                               |                      | ART UNIT            | PAPER NUMBER     |
|                       |                               |                      | 3773                |                  |
|                       |                               |                      |                     |                  |
|                       |                               |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                       |                               |                      | 09/16/2011          | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|
|  | 10/587,099   | BIRK, JANEL A.   |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |
|  | MELISSA RYCKMAN  | 3773   |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | pears on the cover sheet with the c  | orrespondence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |  |  |  |  |  |
| 1) ☐ Responsive to communication(s) filed on 29 J. 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This 3) ☐ Since this application is in condition for allowa closed in accordance with the practice under Expression in the practice of the condition of the practice of the condition of the practice of the condition of the condition of the practice of the condition of the condition of the practice of the condition of the | action is non-final.  nce except for formal matters, pro   |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |
| <ul> <li>4) ☐ Claim(s) 1-4 and 6-21 is/are pending in the application.</li> <li>4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1-4,6-16 and 21 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |  |  |  |  |  |
| Application Papers   |  |  |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.   | epted or b) objected to by the Edination of the Idrawing(s) be held in abeyance. See tion is required if the drawing(s) is obj                                       | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                        |  |  |  |
| Priority under 35 U.S.C. § 119   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |  |  |  |  |
| Attachment(s)  1) Motice of References Cited (PTO-892)   | 4) 🔲 Interview Summary   | (PTO-413)  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date   | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:  | ate  |  |  |  |

### **DETAILED ACTION**

This office action is in response to claims and arguments filed 6/29/11.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,7, 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura (U.S. Patent No. 4,958,791).

Nakamura teaches a releasably-securable adjustable band capable for use as a gastric band capable of being placed laparoscopically around the stomach and capable of being removed from the stomach laparoscopically, comprising:

- a tail end (6', Fig. 2)
- a head end (6, Fig. 2) structured to allow a part of said tail end (most distal end of 6', 31) to be drawn through said head end (31 is drawn through most distal end of 2, 22) to position said tail end within said head end (31 is in 22, Fig. 2)
- a releasable locking means (23 and 31) structured to releasably secure said
  head end (22) to said tail end (31) when said part of said tail end is drawn
  through said head end (31 is drawn through most distal end of 2, 22), to thereby
  releasably secure said releasably-securable adjustable gastric band (21 capable
  of releasing the gastric band) in an encircling position (Fig. 2)

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 a release tab (5, Fig. 1) positioned on said head end (5 is positioned on 6) and structured to allow said releasable locking means (5') to release said tail end (31 and 3) from said head end (22 and 6) when a force is applied to said release tab (capable of being used as described)

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- said releasable locking means includes a tooth (31) formed on a portion of said tail end (31 is formed on 6')
- said releasable locking means includes a notch (23) in said head end for engaging said tooth
- upon insertion of said tail end (31) into said head end (23), said tooth engages
   with said notch and releasably locks said tail end in said head end (Fig. 2)
- application of force to said release tab (5) in a direction substantially
  perpendicular to a central axis of the gastric band allows said tooth (31) to
  disengage from said notch (23) so as to allow the release of said tail end from
  said head end (force applied to 5 as described allows the release)
- wherein application of said force to said release tab (5) lifts said notch (23) over said tooth (31) to allow the release of said tail end (6') from said head end (6, Fig. 2).
- a visual securing indicator (Fig. 2, having 5 and 5' crossing)
- a tactile securing indicator (crossing of 5 and 5', Fig. 2)

Claims 1 and 11-16 is rejected under 35 U.S.C. 102(b) as being anticipated by Kuzmak et al. (U.S. Patent No. 4,592,339).

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Kuzmak teaches a releasably-securable adjustable band for the treatment of obesity (abstract) suitable for laparoscopic placement around the stomach of a patient and suitable fore laparoscopic removal from said stomach (capable of being used as described) comprising:

- a tail end (end near 18, Fig. 1)
- a head end (end near 16, Fig. 1) structured to allow a part of said tail end (part of 18) to be drawn through said head end (through 42, Fig. 4) to position said tail end within said head end (portion of 18 is within 42, Fig. 4)
- a releasable locking means (slot 42) structured to releasably secure said head end (end near 18) to said tail end (end near 16) when said part of said tail end is drawn through said head end, to thereby releasably secure said releasablysecurable adjustable gastric band in an encircling position around said patient's stomach (Fig. 1)
- a release tab (16) positioned on said head end (end near 16 in Fig. 1) and structured to allow said releasable locking means to release said tail end from said head end when a force is applied to said release tab (capable of being used as described)
- said band is adjustable via hydraulic inflation (col. 3, Il. 26)
- said band further comprising an inflation tube (32)
- said tail and head ends comprises said inflation tube (Fig. 5, inflation tube 22 is at the head and tail ends as shown in Figs. 5 and 6)
- said band is mechanically adjustable (pumping more or less fluid, col. 3, Il. 26)

Claims 1, 7-9 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Benchetrit (WO01/85071 all references below will be with U.S. Patent No. 7,824,422, as this is in English).

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Benchetrit teaches a releasably-securable adjustable band for the treatment of obesity suitable for laparoscopic placement around the stomach of a patient and suitable fore laparoscopic removal from said stomach (capable of being used as described) comprising:

- a tail end (end near 25, Fig. 1)
- a head end (end near 6, Fig. 1) structured to allow a part of said tail end (part of
   7) to be drawn through said head end (Fig. 2) to position said tail end within said
   head end (portion of 7 is within 20, Fig. 2)
- a releasable locking means (16) structured to releasably secure said head end
   (end near 6) to said tail end (end near 25) when said part of said tail end is drawn
   through said head end, to thereby releasably secure said releasably-securable
   adjustable gastric band in an encircling position around said patient's stomach
   (Fig. 2)
- a release tab (12) positioned on said head end (end near 6 in Fig. 1) and structured to allow said releasable locking means to release said tail end from said head end when a force is applied to said release tab (capable of being used as described)

• further comprising a visual securing indicator (25, Fig. 1)

- a window (opening 16) for providing positive visual indication when said, head
   end and said tail end are releasably secured together (when 25 is at 16 there is
   positive visual indication of securement, Fig. 2)
- said gastric band is releasably locked in place when said indicator appears in said window following insertion of said tail end into said head end (Fig. 2)
- said band is adjustable via hydraulic inflation (col. 4, Il. 7,8)
- said band further comprising an inflation tube (col. 4, Il. 7,8)
- said tail and head ends comprises said inflation tube (Fig. 2, inflation tube 7 is at the head and tail ends as shown in Fig. 2)
- said band is mechanically adjustable (pumping more or less fluid, col. 4, Il. 7,8)
- said band is remotely adjustable (adjust via 10, Fig. 2)

### Response to Arguments

Applicant's arguments regarding Nakamura filed 6/29/11 have been fully considered but they are not persuasive the applicant's arguments regarding Vincent are persuasive. The applicant generally argues:

Nakamura fails to teach "a head end structured to allow a part of said tail
end to be drawn through said head end to position said tail end within said
head end".

As indicated above: Nakamura teaches a head end (6, Fig. 2) structured to allow a part of said tail end (most distal end of 6', 31) to be drawn through said head end (31

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is drawn through most distal end of 2, 22) to position said tail end within said head end (31 is in 22, Fig. 2).

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)272-9969 and email is Melissa.Ryckman@uspto.gov. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR /Melissa Ryckman/ Examiner, Art Unit 3773

/CORRINE M MCDERMOTT/
Supervisory Patent Examiner, Art Unit 3773